

***Remarks***

Reconsideration of this Application is respectfully requested. Claims 49-52, 55, 60-63, 66, 68, 71-73, 80, 84, 88 and 166-181 are pending in the application, with claim 49 being the independent claim. Claims 182-216 have been canceled without prejudice to their being pursued in a continuing application. Claims 49, 50, 60, 84, 168 and 173-181 have been amended. Support for the claim amendments may be found in the original claims and throughout the specification. No new matter is added by way of these amendments, and their entry is respectfully requested.

Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider and withdraw the outstanding rejections.

***I. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph***

Claims 49-52, 55, 60-63, 66, 68, 71-73, 76, 80, 84, 88 and 166-212 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Office Action, page 3. Although Applicants submit that claims 182-212 are fully definite, they have been canceled in order to facilitate prosecution of the application. Applicants respectfully traverse with respect to the remaining claims.

With respect to claim 49, the Office Action indicated that it was unclear whether “particle size” referred to particle circumference, diameter, volume, surface area or something else. Claim 49 as amended recites that the particles have a diameter of 1-500 nm

inclusive. The Office Action also indicated that the recitation “when each population is on a surface at a particle density of less than 0.1 particles per  $\mu\text{m}^2$  the color scattered light scattered by at least 90% of said particles...” in claim 49 was not clear about what physical or structural characteristics of the particles would be necessary in order to satisfy this recitation. This claim feature is a result of at least the recited particle density and particle size range.

With respect to claims 60 and 88, the Office Action indicated that it was not entirely clear how the coefficient of variation in size would be calculated. The coefficient of variation is a physical property of the particles and is defined in the specification:

“the standard deviation of the particle size distribution divided by the mean of the particle preparation. Thus, for a 60 nm particle preparation with a coefficient of variation of 20%, one standard deviation unit is about  $\pm 12$  nm. This means that about 10% of the particles are smaller than 48 nm or greater than 72 nm.”

See Specification at paragraph [0297]. Thus, since “coefficient of variation” is clearly defined in the specification, the claim need not recite how it should be calculated.

Claim 50 was rejected as indefinite based on the term “significantly.” Although Applicants believe that a person of ordinary skill in the art would realize the metes and bounds of this term, it has been deleted in order to facilitate prosecution of the application.

Claim 60 was rejected as indefinite, since it was alleged to be unclear if the variation in size of less than 5% was between or within populations. Claim 60 as amended recites that the variation is within populations.

The term “about” in claims 76, 80, 84, 173-175, 178, 180, 181, 191-193 and 200-204 was asserted to be a relative term that rendered these claims indefinite. Applicants respectfully note that claims 76 and 80 do not recite “about.” Applicants also note that the term “about” is not a relative term that requires one of skill in the art to consider some indeterminate external reference to understand the metes and bounds of the claimed invention. Rather, skilled artisans can clearly recognize a range of values encompassed around the specifically recited internal values referenced in the claims. Indeed, the Court of Appeals for the Federal Circuit has considered the term “about” definite and has construed the term in at least the following cases: Hilton Davis Chemical Co. c. Warner – Jenkinson Co., Inc., 62 F.3d 1512, 35 USPQ2d 1641 (Fed. Cir. 1995) (in bane), rev’d & remanded, 520 U.S.17, 41 USPQ2d 1865 (1997), remanded, 114 F.3d 1161, 43 USPQ2d 1152 (Fed. Cir. 1997) (Order Per Curiam); W.L. Gore & Associates Inc. c. Garlock Inc., 842 F.2d 1275, 6 USPQ2d 1277 Fed. Cir 1988; Conoco, Inc. v. May Department Stores Co., 46 F.3d 1556, 32 USPQ2d 1225 (Fed. Cir 1994), cert. denied, 514 U.S. 1078 (1995); Eiselstein v. Frank, 52 F.3d 1035, 34 USPQ2d 1467 (Fed. Cir. 1995); Quantum Corp. v. Rodine, Plc, 65 F.3d 1577, 36 USPQ2d 1162 (Fed. Cir. 1995), cert. denied, 517 U.S. 1167 (1996); Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 36 USPQ2d 1225 (Fed. Cir. 1995), cert. denied, 520 U.S. 1115 (1997); and BJ Services Co. v. Halliburton Energy Services, Inc., 338 F.3d 1368, 67 USPQ2d 1692 (Fed. Cir. 2003).

Claims 167 and 184 were rejected as indefinite since it was allegedly unclear what physical or structural characteristics would be necessary in order for the color of the scattered light scattered by two or more populations to be distinguishably different. Claim

167 was also rejected as indefinite based on the term “distinguishably,” and since it was allegedly unclear whether the binding agent is capable of binding to a variety of different analytes, or if the binding agent of each population binds to a different analyte. Claim 184 has been canceled, thus rendering its rejection moot. With respect to claim 167, Applicants note that this claim as amended no longer recites “distinguishably different,” but rather that there is a detectable difference in color. The specification provides adequate guidance as to what a detectable difference is, and from what properties of the populations such a difference arises (see e.g., paragraphs [0232] and [0233]). Finally, claim 167 as amended recites that the binding agent on each population of particles is different to clarify that each binding agent of each population binds to a different analyte.

Claim 215 was rejected as indefinite, since it was allegedly unclear what materials would provide chemical stability. Claim 215 has been canceled herein.

In view of the amendments and comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

## ***II. Claim Rejections Under 35 U.S.C. § 112, First Paragraph***

Claims 174 and 175 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, it was alleged that no support was found for gold or silver coatings thinner than 19 nm. Applicants

respectfully direct the Examiner to Tables 13-15, which provide support for all of the surface coating thicknesses recited in claims 174 and 175.

Applicants therefore request that the rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

***III. Claim Rejections Under 35 U.S.C. § 102***

**Mroczkowski (U.S. 5,137,827)**

Claims 49-52, 55, 61-63, 66, 68, 76, 80, 84, 166-173 and 176-179 were rejected under 35 U.S.C. § 102(b) as being anticipated by Mroczkowski (U.S. 5,137,827). Claim 49 as amended recites that “the color of scattered light scattered by at least 90% of said particles of each said population upon illumination of each said population on a surface at a particle density of less than 0.1 particles per  $\mu\text{m}^2$  with white light is indistinguishable to the human eye when viewed with less than 500 times magnification and without electronic amplification...” The remainder of the claims depend directly or indirectly from claim 49. Mroczkowski fails to disclose this feature.

The recitation in claim 49 of “when each said population is on a surface at a particle density of less than 0.1 particles per  $\mu\text{m}^2$  and illuminated with white light, the color of scattered light scattered by at least 90% of said particles of each said population is indistinguishable to the human eye when viewed with less than 500 times magnification and without electronic amplification” was not given patentable weight in the Office Action as being only an intended use the populations of particles. While Applicants disagree with this

characterization, claim 49 has been amended to more positively recite what is a physical property, and not an intended use, of the particles. The light-scattering behavior of the particle populations, such that when they are illuminated on a surface at the recited particle density, the color of scattered light scattered by at least 90% of the particles of each population is indistinguishable” is a physical property of the particles and cannot be considered an “intended use.” In fact, an “intended use” of the particles is for analyte detection as discussed throughout the specification (see e.g., paragraphs [0079], [0080], [0086], [0481], and [0486]).

Because the light scattering feature of the claimed particles is not disclosed by Mroczkowski, Applicants respectfully request that this rejection under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

**Rembaum (U.S. 4,929,400)**

Claims 49-52, 55, 60, 63, 66, 71-73, 76, 80, 84, 88, 166-173, 176-179, 182-191, 196, 198, and 205-215 were rejected under 35 U.S.C. § 102(b) as being anticipated by Rembaum (U.S. 4,929,400). Claim 49 as amended recites that “the color of scattered light scattered by at least 90% of said particles of each said population upon illumination of each said population on a surface at a particle density of less than 0.1 particles per  $\mu\text{m}^2$  with white light is indistinguishable to the human eye when viewed with less than 500 times magnification and without electronic amplification...” The remainder of the pending claims depend directly or indirectly from claim 49.

Because the light scattering feature of the claimed particles is not disclosed by Rembaum, Applicants respectfully request that this rejection under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

**Margel (U.S. 4,624,923)**

Claims 48-52, 55, 61-63, 68, 71-73, 76, 80, 84, 166-173 and 176-179 were rejected under 35 U.S.C. § 102(b) as being anticipated by Margel et al. (U.S. 4,624,923). Claim 49 as amended recites that “the color of scattered light scattered by at least 90% of said particles of each said population upon illumination of each said population on a surface at a particle density of less than 0.1 particles per  $\mu\text{m}^2$  with white light is indistinguishable to the human eye when viewed with less than 500 times magnification and without electronic amplification...” The remainder of the pending claims depend directly or indirectly from claim 49.

Because the light scattering feature of the claimed particles is not disclosed by Margel, Applicants respectfully request that this rejection under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

**Tarcha (U.S. 5,567,628)**

Claims 49-52, 55, 62, 66, 68, 76, 80, 84, 166-173, 176-179 and 181 were rejected under 35 U.S.C. § 102(e) as being anticipated by Tarcha (U.S. 5,567,628). Claim 49 as amended recites that “the color of scattered light scattered by at least 90% of said particles of each said population upon illumination of each said population on a surface

at a particle density of less than 0.1 particles per  $\mu\text{m}^2$  with white light is indistinguishable to the human eye when viewed with less than 500 times magnification and without electronic amplification..." The remainder of the pending claims depend directly or indirectly from claim 49.

Because the light scattering feature of the claimed particles is not disclosed by Tarcha, Applicants respectfully request that this rejection under 35 U.S.C. § 102(e) be reconsidered and withdrawn.

***IV. Claim Rejections Under 35 U.S.C. § 103 (a)***

**Tarcha (U.S. 5,567,628)**

Claims 60, 88, 180, 182-184, 186-191, 194-199, 201-208 and 212-216 were rejected as being unpatentable over Tarcha (U.S. 5,567,628). Claims 182-184, 186-191, 194-199, 201-208 and 212-216 have been canceled, thus rendering the rejection moot with respect to these claims. Claims 60, 88 and 180 depend from claim 49 which recites that "the color of scattered light scattered by at least 90% of said particles of each said population upon illumination of each said population on a surface at a particle density of less than 0.1 particles per  $\mu\text{m}^2$  with white light is indistinguishable to the human eye when viewed with less than 500 times magnification and without electronic amplification..." The remainder of the pending claims depend directly or indirectly from claim 49.

Establishing *prima facie* obviousness requires a showing that each claim element is taught or suggested by the prior art. See *In re Royka*, 490 F.2d 981, 180 USPQ 580



(CCPA 1974). Specifically, establishing *prima facie* obviousness requires a showing that some combination of objective teachings in the art and/or knowledge available to one of skill in the art would have lead that individual to arrive at the claimed invention. *See In re Fine*, 5 USPQ2d 1596,1598 (Fed. Cir. 1988). Moreover, establishing *prima facie* obviousness requires not only a showing that such a combination of prior art teachings is possible, but also that the teachings would have 1) motivated the skilled artisan to make the combination to arrive at the claimed invention, and 2) suggested to the skilled artisan a reasonable likelihood of success in making and using the claimed invention. *See In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). Absent a showing of such motivation and suggestion, *prima facie* obviousness is not established. *See Fine*, 5 USPQ2d at1598.

Since Tarcha neither discloses nor suggests the light scattering feature of the claimed particles, a *prima facie* case of obviousness has not been established. Applicants therefore respectfully request that this rejection under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

**Mroczkowski (U.S. 5,137,827)**

Claims 60, 88, 174, 175, 182-184, 193, 196-202, 205-208 and 212-216 were rejected as being unpatentable over Mroczkowski (U.S. 5,137,827). Claims 174, 175, 182-184, 193, 196-202, 205-208 and 212-216 have been canceled, thus rendering the rejection moot with respect to these claims. Claims 60 and 88 depend from claim 49 which recites that “the color of scattered light scattered by at least 90% of said particles

of each said population upon illumination of each said population on a surface at a particle density of less than 0.1 particles per  $\mu\text{m}^2$  with white light is indistinguishable to the human eye when viewed with less than 500 times magnification and without electronic amplification..." The remainder of the pending claims depend directly or indirectly from claim 49.

Since Mroczkowski neither discloses nor suggests the light scattering feature of the claimed particles, a *prima facie* case of obviousness has not been established. Applicants therefore respectfully request that this rejection under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

**Margel (U.S. 4,624,923) in view of Mroczkowski (U.S. 5,137,827)**

Claims 181-182 and 203-204 were rejected as being unpatentable over Margel (U.S. 4,624,923) in view of Mroczkowski (U.S. 5,137,827). Claims 182 and 203-204 have been canceled, thus rendering this rejection moot with respect to these claims. Claim 181 depends indirectly on claim 49 which recites that "the color of scattered light scattered by at least 90% of said particles of each said population upon illumination of each said population on a surface at a particle density of less than 0.1 particles per  $\mu\text{m}^2$  with white light is indistinguishable to the human eye when viewed with less than 500 times magnification and without electronic amplification..."

Since Margel and Mroczkowski neither disclose nor suggest the light scattering feature of the claimed particles, a *prima facie* case of obviousness has not been

established. Applicants therefore respectfully request that this rejection under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

**Margel (U.S. 4,624,923)**

Claims 60, 88, 174, 175, 182-184, 193, 196-202 and 205-216 were rejected as being unpatentable over Margel (U.S. 4,624,923). Claims 174, 175, 182-184, 193, 196-202 and 205-216 have been canceled, thus rendering the rejection moot with respect to these claims. Claims 60 and 88 depend from claim 49 which recites that “the color of scattered light scattered by at least 90% of said particles of each said population upon illumination of each said population on a surface at a particle density of less than 0.1 particles per  $\mu\text{m}^2$  with white light is indistinguishable to the human eye when viewed with less than 500 times magnification and without electronic amplification...” The remainder of the pending claims depend directly or indirectly from claim 49.

Since Margel neither discloses nor suggests the light scattering feature of the claimed particles, a *prima facie* case of obviousness has not been established. Applicants therefore respectfully request that this rejection under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

**Margel (U.S. 4,624,934) in view of Tarcha (U.S. 5,567,628)**

Claims 181, 182, 203 and 204 were rejected as being unpatentable over Margel (U.S. 4,624,934) in view of Tarcha (U.S. 5,567,628). Claims 182, 203 and 204 have been canceled, thus rendering this rejection moot with respect to these claims. Claim

181 depends indirectly on claim 49 which recites that “the color of scattered light scattered by at least 90% of said particles of each said population upon illumination of each said population on a surface at a particle density of less than 0.1 particles per  $\mu\text{m}^2$  with white light is indistinguishable to the human eye when viewed with less than 500 times magnification and without electronic amplification...”

Since Margel and Tarcha neither disclose nor suggest the light scattering feature of the claimed particles, a *prima facie* case of obviousness has not been established.

Applicants therefore respectfully request that this rejection under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

***Conclusion***

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

Date: December 20, 2004

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